IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP. Defendants.	)	Civ. No. 13-1461-RGA **Redacted Version D.I. 82**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS

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Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") ("collectively, "Plaintiffs"), pursuant to Fed. R. Civ. P. 12(b)(1) and Fed. R. Civ. P. 41(a)(2), respectfully request that this Court grant Plaintiffs' Motion to Dismiss, without prejudice, all claims in this action against Defendants Par Pharmaceuticals, Inc. ("Par") and IntelGenX Technologies Corp. ("IntelGenX") (collectively, "Defendants"), as well as all of Defendants' counterclaims against Plaintiffs.

I. INTRODUCTION

Just last month, this Court, at the request of a plaintiff brand pharmaceutical company, dismissed without prejudice the plaintiff's patent infringement suit under 35 U.S.C. § 271(e)(2) against the filer of an Abbreviated New Drug Application ("ANDA") because the ANDA filer had prematurely served its Paragraph IV notice on the plaintiff without first having received an acceptance of filing letter from the U.S. Food and Drug Administration (FDA) that the ANDA was sufficiently complete for review, as is required by the Hatch Waxman statute, 35 U.S.C. § 355(j)(2)(B)(ii)(II). (Severance Decl.[1], Ex. A [D.I. 24, Order, in *Otsuka Pharm. Co. Ltd. v. Par Pharm., Inc.*, No. 13-1979 (D. Del. March 10, 2014)].) Since the Paragraph IV notice was premature, untimely and ineffective, it failed to trigger the Hatch Waxman litigation process and therefore did not give rise to subject matter jurisdiction under 35 U.S.C. § 271(e)(2). (*Id.*)

Here, Defendants are in exactly the same position as was the ANDA filer in *Otsuka.* Par admittedly served the Paragraph IV certifications on which this action is based even though its application had not been accepted for filing when it started the litigation process. Therefore, these Paragraph IV certifications were premature, untimely, and ineffective and, just as in

[1] The "Severance Decl." refers to the Declaration of Dana K. Severance in Support of Plaintiffs' Motion to Dismiss, filed concurrently.

Otsuka, failed to give rise to subject matter jurisdiction under 271(e)(2). Accordingly, all the claims in this action, including Defendants' counterclaims, should be dismissed without prejudice. (*Id.*)

Par's trade secret counterclaim should also be dismissed without prejudice. MonoSol did not assert a claim in its complaint against Par for trade secret misappropriation. Plaintiffs have alleged patent infringement. Since the filing of the patent infringement case, MonoSol has repeatedly affirmed that no allegations of trade secret misappropriation have been made against Par. The lack of any concrete dispute between the Parties is underscored by the fact that Plaintiffs have not even determined whether Par has misappropriated MonoSol's trade secrets. As there is no actual controversy regarding trade secret misappropriation, Par's trade secret counterclaim should be dismissed without prejudice for lack of subject matter jurisdiction.

II. BACKGROUND

A. Par Improperly Proceeded Through The Hatch-Waxman Statutory Scheme

1. The ANDA Litigation Process

Pharmaceutical companies must obtain approval from the FDA in order to market a new drug in the United States. This is typically accomplished through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a); [D.I. 56 [Amended Complaint (hereinafter "Complaint")] ¶¶ 18-19. The NDA sponsor company must submit information to the FDA pertaining to all patents claiming the drug, or a method of using the drug, that is the subject of the NDA. 21 U.S.C. § 355(b)(1) and (c)(2). The FDA subsequently records that patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2); Complaint ¶ 20.

When a generic drug manufacturer seeks to produce a generic version of a previously approved drug, the manufacturer must file an Abbreviated New Drug Application ("ANDA") instead of an NDA. *See* 21 U.S.C. § 355(j); Complaint ¶¶ 21-29. Approval of a generic drug is abbreviated because the generic manufacturer is permitted to rely on the NDA sponsor company's data as well as the FDA's prior findings of safety and efficacy, which can be achieved, for example, by demonstrating that the generic drug is bioequivalent to the previously approved drug.

In addition to the abbreviated application process for generic drugs, Congress implemented a statutory process to resolve patent disputes between NDA sponsor companies and generic drug manufacturers, wherein the ANDA filer must provide specific certifications, known as "Paragraph IV Certifications," for each patent listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12); Complaint ¶¶ 21-29. The ANDA filer may certify its belief that a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug that is the subject of the ANDA. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

After submitting an ANDA to the FDA, the FDA must preliminarily review the application within 60 days and notify the applicant that the ANDA is sufficiently complete—it is only at this point at which the ANDA is deemed to have been filed. 21 C.F.R. § 314.101. When an ANDA has been accepted for review by the FDA, the generic drug company must provide notice ("Paragraph IV Notice") to the owner of the listed patent and the holder of the NDA for the reference listed drug. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95; Complaint ¶¶ 21-29. Paragraph IV Notices must detail the factual and legal bases for the generic company's belief that the challenged patent is invalid and/or not infringed by the proposed generic drug. *Id.*

Federal regulations require that Paragraph IV Notices be sent ***only after*** the FDA has officially received the ANDA and deemed it sufficiently complete for review. 21 U.S.C. § 355(j)(2)(B)(ii); 21 C.F.R. § 314.95(b).

If, after receiving a timely Paragraph IV Notice from an ANDA filer, the patentee or NDA holder files a patent infringement suit within 45 days, final approval of the ANDA is subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(2)(B)(iii); 21 C.F.R. § 314.107(b)(3); Complaint ¶¶ 27, 29. The 30-month stay is critical to companies like Plaintiffs, because it prevents extreme financial injury that could otherwise result from FDA approval of an infringing product before allowing time for an appropriate resolution of the infringement case. *See* 21 U.S.C. § 355(j)(2)(B)(iii).

Generic drug companies are highly incentivized to prematurely submit incomplete ANDA filings, given that the earliest ANDA filer may be granted 180 days of generic exclusivity, during which time other ANDA filers are prohibited from competing with rival generic drugs. *See* 21 U.S.C. § 355(j)(2)(B)(iv). Premature filing, or prematurely notifying the NDA holder or patent owner, allows the ANDA filer the potential to market its generic drug much earlier than ordinarily allowed. *Id.* As such, improper notification unnecessarily obliges the NDA holder or patent owner to expend significant resources in support of an infringement suit that, if the ANDA were ultimately denied review by the FDA, would have been entirely unnecessary. Furthermore, an ANDA filer that has not received an acceptance for filing letter from FDA as to its subject ANDA should not be allowed to reap any strategic advantage from having prematurely triggered the Hatch Waxman litigation process as a result of serving a premature, untimely Paragraph IV Notice.

Accordingly, one of the important protections built into the ANDA process is that a

generic applicant may not send a Paragraph IV Notice until it "receives from the FDA an acknowledgement letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b); *see also* 21 U.S.C. § 355(j)(2)(B)(ii). This regulatory and statutory safeguard prevents the service of a Paragraph IV Notice based on an incomplete or insufficient ANDA which may trigger unnecessary litigation, provide an improper and unjustified strategic benefit to the ANDA filer, and prejudice both the innovator company and other ANDA filers whose rights to exclusivity may be compromised. Consequently, an ANDA applicant may not serve a Paragraph IV Notice prior to its receipt of the FDA's letter notifying them that the subject ANDA is sufficiently complete and has been accepted for substantive review.

2. Prior To Its Purported Notice Letters, Par Had Not Received An Acceptance Of Filing Letter From The FDA For Its ANDA

Par sent Plaintiffs a Paragraph IV Notice dated July 8, 2013 stating that Par had submitted ANDA No. 20-5954 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of buprenorphine hydrochloride and naloxone hydrochloride sublingual film, a generic version of Plaintiffs' Suboxone® sublingual film, before expiration of Plaintiffs' patents.[2] (Complaint ¶¶ 21-22; D.I. 62 [Answer] ¶ 21-22.) The letter further provided that Par's ANDA No. 20-5954 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '832 and '150 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA. (Complaint ¶ 21; Answer ¶ 21.)

[2] This action was originally commenced within 45 days of the July 8, 2013 Notice. Before the suit was filed, Par's counsel informed Plaintiffs' counsel that Par had not received an acceptance of filing letter for its ANDA from FDA. Plaintiffs commenced suit, however, in order to protect their rights, including with respect to obtaining the 30-month stay of FDA marketing approval for Par's ANDA provided under the Hatch Waxman framework.

Par sent Plaintiffs another Paragraph IV Notice dated February 3, 2014,[3] stating that ANDA No. 20-5954 contains a Paragraph IV Certification alleging that the '514 patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in Par's ANDA. (Complaint ¶ 28; Answer ¶ 28.) This Notice further states that ANDA No. 20-5954 seeks approval to engage in commercial manufacture, use, and/or sale of Par's generic product before expiration of the '514 Patent. (Complaint ¶ 28; Answer ¶ 28.)

On February 18, 2014, Plaintiffs filed an Amended Complaint within 45 days of receiving Par's February 3, 2014 Notice regarding the '514 Patent.

On February 28, 2014, Plaintiffs sent an interrogatory to Par requesting information as to whether Par had received an acceptance for filing letter (sometimes referred to as an AFF letter) for its ANDA. On March 31, 2014, Par responded that it first received an AFF or acceptance for filing letter for its subject ANDA on REDACTED (Severance Decl., Ex. B [Defendant Par Pharmaceutical, Inc.'s Responses to Plaintiffs' First Set of Joint Interrogatories] at Interrogatory No. 1.)

After this litigation began, Plaintiffs received yet another letter from Par dated March 25, 2014, repeating that ANDA No. 20-5854 contains a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '832, '150, and '514 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA. (D.I. 9 [Am. Compl.] ¶ 43 in *Reckitt Benckiser Pharms., Inc. et al. v. Par Pharm., Inc. et al.*, No. 14-422-RGA.) The letter further states that Par submitted ANDA No. 20-5854 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and/or sale of Defendants' generic product—*i.e.*, buprenorphine

[3] The Notices, dated July 8, 2013 and February 3, 2013, are collectively referred to as the "Purported Notice Letters."

hydrochloride and naloxone hydrochloride sublingual film—before expiration of the patents-in-suit. (D.I. 9 [Am. Compl.] ¶ 44 in *Reckitt Benckiser Pharms., Inc. et al. v. Par Pharm., Inc. et al.*, No. 14-422-RGA.)

Unlike the Purported Notice Letters, the March 2014 Notice Letter represents that the FDA "has received [ANDA No. 20-5854] for substantive review."

In response to the March 25, 2014 Notice Letter, on April 4, 2014, Plaintiffs filed a Complaint against Par in the District of Delaware, Case Number 1-14-cv-00422, seeking a declaratory judgment that:

> (1) Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are premature, null and void, and ineffective to trigger the ANDA patent litigation process in this litigation;
>
> (2) Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, did not trigger the 45-day period for filing an infringement action and the 30-month injunction on FDA approval of Defendants' ANDA No. 20-5854; and
>
> (3) there is no subject matter jurisdiction over Plaintiffs' claims and Defendants' counterclaims in this litigation because Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are null and void.

(D.I. 9 [Am. Compl.] ¶ 59 in *Reckitt Benckiser Pharms., Inc. et al. v. Par Pharm., Inc. et al.*, No. 14-422-RGA; *see also* D.I. 1 [Compl.] ¶ 49-54, Prayer for Relief in *Reckitt Benckiser Pharms., Inc. et al. v. Par Pharm., Inc. et al.*, No. 14-422-RGA).

B. Plaintiffs Have Not Alleged That Par Misappropriated Trade Secrets

On September 24, 2013, Par filed a counterclaim for declaratory judgment that Par has not misappropriated any trade secret of MonoSol. (D.I. 15 [Countercl.] ¶¶ 39-52.) As the factual

basis for its counterclaim, Par pointed to a single statement in a letter from Plaintiffs dated August 2, 2013.[4] (*Id.* at ¶¶ 32, 41.) The August 2 letter reads, in relevant part:

> "…under prior agreements MonoSol has provided Par with information relating to its manufacturing practices and know how. As a result, MonoSol needs to be able to consider trade secret issues in addition to patent issues under the OCA and requests that 2.C expressly so provide for purposes of clarity."

(D.I. 45-1 [Exs. A-K to Jan. 27, 2014 Fineman Letter to Court regarding discovery dispute] at Exhibit C, page 2.) Contrary to Par's characterization, after reviewing the August 2 letter, this Court said the cited statement in the August 2 letter was not a trade secrets assertion; "in fact, there have been no trade secrets assertions."[5] (D.I. 75-2 [Ex. 2, Jan. 31, 2014 Hearing Tr.] at 27:20-23).

The fact that MonoSol has not asserted trade secret misappropriation has been continuously echoed by Plaintiffs throughout this litigation. At the very start of this case, Plaintiffs did not assert a trade secret misappropriation claim. (D.I. 1 [Compl.].) Rather, Par injected the trade secrets issue into the case by filing a declaratory judgment counterclaim.[6] (D.I. 15 [Countercl.] at ¶¶ 39-52.) In response to the counterclaim, Plaintiffs expressly denied "making any allegation that Par has misappropriated trade secrets." (D.I. 20 [Ans. to Countercl.] ¶¶ 47-48.)

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[4] The August 2 letter was in the context of negotiations concerning the wording of the Offer for Confidential Access that would precede the transmittal of Par's ANDA to Plaintiffs.

[5] As explained by the author, the August 2 letter was intended to prevent MonoSol from being foreclosed from considering trade secret issues once it had access to Par's ANDA. (D.I. 75-2 [Ex. 2, Jan. 31, 2014 Hearing Tr.] at 18:19-20:5). "[A]t no time did either of the Plaintiffs allege that Par actually had used trade secrets – of – of MonoSol's whether – whether during the OCA process or during this lawsuit." (*Id.* at 20:2-5.)

[6] Par's counterclaim seeks a declaration that it did not misappropriate any MonoSol trade secret. This is the reverse of a typical trade secret claim and wrongly seeks to shift the burden to MonoSol to identify its trade secrets when MonoSol has not even alleged any misappropriation.

At the Rule 16 Scheduling Conference, counsel for MonoSol reiterated that Plaintiffs did not "bring a trade secret claim because we don't know what they're using or what technology they're using in their product." (D.I. 29 [Dec. 13, 2013 Hearing Tr.] at 53:22-54:1; *see also id.* at 60:8-10).

The lack of contention was affirmed multiple times. In its January 29, 2014 letter, MonoSol definitively stated, "MonoSol has not alleged and does not contend Par has misappropriated any trade secrets." (D.I. 48 [Jan. 29, 2014 Bourke Letter to Court regarding discovery dispute] at 3.) On the very next day, MonoSol reiterated that "MonoSol has not accused Par of stealing its trade secrets." (D.I. 50 [Jan. 30, 2014 Bourke Letter to Court regarding discovery dispute] at 1.) At the hearing addressing this issue, MonoSol's counsel once again said, "MonoSol has never made an assertion that it's [sic] trade secrets have been misappropriated." (D.I. 75-2 [Ex. 2, Jan. 31, 2014 Hearing Tr.] at 12:23-25). Most recently, on April 4, 2014, MonoSol restated, "MonoSol has never alleged that Par misappropriated its trade secrets." (D.I. 75 [April 4, 2014 Bourke Responsive Letter to Court regarding discovery dispute] at 2.)

III. ARGUMENT

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a claim for lack of jurisdiction over the subject matter. *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Motions brought under Rule 12(b)(1) may present either a facial or factual challenge to the court's subject matter jurisdiction. *Mayfair Wireless v. Celico P'ship.*, No. 11-772, 2013 U.S. Dist. LEXIS 124206, at *8 (D. Del. Aug. 30, 2013). Facial challenges attack the complaint on its face. *Mortensen*, 549 F.2d at 891. Factual challenges, such as this challenge, attack the existence of subject matter jurisdiction in fact, and apart from any pleadings. *Id.*

Because the trial court's jurisdiction is at issue in a factual 12(b)(1) motion, "there is substantial authority that the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Id.*

Federal Rule of Civil Procedure 41(a)(2) authorizes voluntary dismissal of a claim and provides: "[A]n action may be dismissed at the plaintiff's request only by court order, on terms that the court considers proper. If a defendant has pleaded a counterclaim before being served with the plaintiff's motion to dismiss, the action may be dismissed over the defendant's objection only if the counterclaim can remain pending for independent adjudication."[7] "When a plaintiff moves for a dismissal without prejudice under Rule 41(a)(2), the decision to dismiss with prejudice or without is left to the discretion of the court." *Benitec Austl. Ltd. v. Nucleonics, Inc.*, No. 04-0174, 2005 U.S. Dist. LEXIS 22008, at *3 (D. Del. Sept. 29, 2005). A Rule 41(a)(2) motion "will be determined after attempting to secure substantial justice to both parties." *Id.* at *4. In considering the legitimate interests of both parties, "the Court must bear in mind that a plaintiff's motion should be granted absent substantial prejudice to the defendant." *Id.*

A. The Court Should Dismiss this Action Without Prejudice because It Lacks Subject Matter Jurisdiction in View Of Par's Improper Triggering of The ANDA Litigation Process

The Purported Notice Letters that Par sent to Plaintiffs in regard to its subject ANDA were improper, premature, untimely, void and ineffective because at no time prior to its service of the Purported Notice Letters did Par have an acceptance of filing letter for its ANDA from FDA. Such notice letters are effective to trigger the ANDA litigation process under the Hatch Waxman statute ***only after*** the ANDA filer has received such a letter from FDA stating that the ANDA is sufficiently complete to permit a substantive review and that is been accepted for filing

[7] For reasons described herein, Par's counterclaims should be dismissed along with Plaintiffs' claims.

on that basis.

The timing for provision of a Paragraph IV notice by an ANDA filer is governed by 21 U.S.C. § 355(j)(2)(B)(ii)(I):

> An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph -- (I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed.

The corresponding federal regulation construing this provision provides:

> The applicant shall send the notice required by paragraph (a) of this section when it receives from FDA an acknowledgment letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review.

21 C.F.R. § 314.95(b). The directive is unambiguous—before sending a Paragraph IV Notice to the patent owner and NDA holder, the ANDA filer must receive acknowledgement from the FDA that its ANDA has been filed (*i.e.*, is sufficiently complete to permit substantive review).

The legislative history of the Hatch-Waxman Act reveals policy considerations articulated by both Congress and the FDA regarding the importance of timing of Paragraph IV Notices. "Congress did not intend that applicants be permitted to circumvent this notice requirement [proposed 21 C.F.R. § 314.95(b)] by filing sham ANDA's or ANDA's which are substantially incomplete." *SB Pharmco Puerto Rico, Inc. v. Mutual Pharm. Co.*, 552 F. Supp. 2d 500, 507 (E.D. Pa. 2008) (citing 59 Fed. Reg. 50,338, 50,349 (Oct. 3, 1994) (quoting H. R. REP. NO. 98-857, at 24 (1984))) (internal quotations omitted). The FDA expressed similar concerns:

> To permit an ANDA applicant to provide notice [to the patentee] before FDA has determined whether the ANDA is sufficiently complete would be contrary to the legislative history because it would only encourage ANDA applicants to file incomplete or 'sham' ANDA's and to supplement them later to secure a place in the review queue in an attempt to secure the first ANDA approval.

SB Pharmco, 552 F. Supp. 2d at 508 (citing 59 Fed. Reg. 50,338, 50,350 (Oct. 3, 1994)). In *SB Pharmco*, the generic ANDA filer sent Paragraph IV notices, before its underlying ANDA was accepted by the FDA for filing. The court cited correspondence from the FDA interpreting 21 U.S.C. § 355(j)(2)(B)(ii)(II):

> Notice of paragraph IV certification submitted in an amendment or supplement to an ANDA is to be sent "at the time" the amendment or supplement is submitted to the agency. Section 505(j)(2)(B)(ii)(II). Notice in this context does not raise the same concerns about premature notice because the agency will have already determined under 21 CFR 314.101 that the application being amended or supplemented is sufficiently complete to permit review.

SB Pharmco, 552 F. Supp. 2d at 510 (citation omitted). The court also noted that reading the entire provision in its entirety,[8] "it seems clear that subparagraph (II) refers to an amendment to an ANDA for which the FDA has already acknowledged receipt." *Id*. at 509 n. 4. The court interpreted 21 U.S.C. § 355(j)(2)(B)(ii)(II) to mean that notice be sent simultaneously with the amendment or supplement "only if the amendment is submitted for an ANDA that has already been accepted for filing." *Id*. at 510. The court concluded that the ANDA filer's Paragraph IV Notice was not valid or timely under 21 U.S.C. § 355(j)(2)(B)(ii)(II). As a result of the invalid, untimely Paragraph IV Notice, the court dismissed without prejudice the patentee's alternative counts of infringement and the defendant's counterclaims. *Id*. at 511.

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[8] 21 U.S.C. § 355(j)(2)(B)(ii) states:

> (ii) Timing of notice. An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph--
>
> (I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or
>
> (II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

This Court recently came to the same conclusion and afforded the same relief in the *Otsuka* case, where Par also sent premature Paragraph IV notices. In *Otsuka,* Par admitted that it sent Paragraph IV Notices to Otsuka prior to the ANDA being accepted for review by the FDA. (Severance Decl., Ex. C [D.I. 23, Otsuka Reply in *Otsuka*, No. 13-1979 (D. Del. March 7, 2014)] at 1.) Since those Paragraph IV Notices were premature and invalid, failed to trigger the ANDA litigation process, and thus failed to give rise to subject matter jurisdiction, the Court dismissed without prejudice Otsuka's patent infringement claims and Par's declaratory judgment counterclaims. (Severance Decl., Ex. A; Severance Decl., Ex. D [D.I. 15, Otsuka Opening Brief in *Otsuka*, No. 13-1979 (D. Del. Jan. 16, 2014)] at 1, 15-16.)

This Court's ruling in *Otsuka* is fully consistent with the position of the FDA:

> FDA has not interpreted [the amendment provision] to require or permit applicants who amend their applications before receipt of an acknowledgement letter to provide notice before learning whether their application has been determined to be sufficiently complete to be received. Rather, this provision applies only to amendments made after an ANDA has been received.

(Severance Decl., Ex. E [August 15, 2012 letter from the FDA], available at http://www.hpm.com/pdf/blog/Par%20Premature%20Notice%20Ltr.pdf (last visited April 16, 2014).) Concluding that the premature notification was invalid and did not trigger the 45-day litigation window or 30-month stay, the FDA explained its rejection of the ANDA filer's (Par's) reliance on the amendment provision as follows:

> The requirement that the ANDA applicant wait to send notice until it receives confirmation from the FDA that the application meets the requirements for review (i.e., may be "received") ensures that the NDA holder and patent owner do not needlessly expend resources to initiate litigation with respect to an ANDA that is incomplete and therefore may not be reviewed by the agency. . . . The agency believes Congress did not intend that incomplete application submissions would trigger legal action by a patent owner or NDA holder and therefore we implemented this interpretation of the notice requirement.

(*Id*. at Ex. E at 1-2.)

Thus, Par's Purported Notice Letters were not timely or valid or effective; they were premature and ineffective to trigger the ANDA litigation process because Par did not receive an acceptance of filing letter from FDA before sending any of the Purported Notice Letters to Plaintiffs.

Accordingly, in the absence of an effective Paragraph IV Notice this Court lacks subject matter jurisdiction over the claims in this ANDA litigation and the same relief that this Court afforded in *Otsuka* should be granted here. Plaintiffs' infringement claims against Defendants should be dismissed without prejudice, pursuant to Rule 41(a)(2) and Defendants' counterclaims[9] should be dismissed without prejudice, pursuant to Rule 12(b)(1).

B. The Court Should Dismiss This Action Without Prejudice Because It Lacks Subject Matter Jurisdiction As There Is Not An Actual Controversy Regarding Trade Secrets

In order for subject matter jurisdiction to exist in a declaratory judgment case, an actual controversy must exist between the parties. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007). "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127 (quoting *Md. Cas. Co. v. P. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). The dispute must be definite and concrete, touching the legal relations of the parties having adverse legal interests—*i.e.*, it must be real and substantial and admit of specific relief

[9] Par's counterclaim for a declaration that Par is not misappropriating MonoSol's trade secrets is presumably being brought pursuant to Delaware state law. (D.I. 15 [Answer] ¶ 43). If the Court dismisses Plaintiffs' infringement claims against Defendants and Defendants' related patent counterclaims, federal jurisdiction over Par's trade secret counterclaim would be absent. Accordingly, the trade secret counterclaim should also be dismissed, pursuant to 28 U.S.C. § 1367(c)(3).

through a decree of a conclusive character, as distinguished from an opinion advising what the law would be based on a hypothetical state of facts. *Id.*

No actual controversy exists between MonoSol (let alone any of the Plaintiffs) and Par regarding trade secret misappropriation.[10] At a minimum, for an actual controversy to exist, MonoSol and Par must have adverse legal positions. *MedImmune*, 549 U.S. at 127 (citation omitted). In other words, as Par has taken the position that it has not misappropriated MonoSol's trade secrets, MonoSol must allege that Par has misappropriated MonoSol's trade secrets for an actual controversy to exist. But MonoSol has not alleged that Par misappropriated MonoSol's trade secrets. This point has been consistently and repeatedly made. (D.I. 20 [Ans. to Countercl.] ¶ 47 ("Plaintiffs deny making any allegation that Par has misappropriated trade secrets."); D.I. 48 [Jan. 29, 2014 Bourke Letter to Court regarding discovery dispute] at 3 ("MonoSol has not alleged and does not contend Par has misappropriated any trade secrets."); D.I. 50 [Jan. 30, 2014 Bourke Letter to Court regarding discovery dispute] at 1 ("MonoSol has not accused Par of stealing its trade secrets."); D.I. 75-2 [Ex. 2, Jan. 31, 2014 Hearing Tr.] at 12:23-25 ("MonoSol has never made an assertion that it's [sic] trade secrets have been misappropriated."); D.I. 75 [April 4, 2014 Bourke Responsive Letter to Court regarding discovery dispute] at 2 ("MonoSol has never alleged that Par misappropriated its trade secrets.") Driving this point home, MonoSol did not file a claim against Par for trade secret misappropriation. (D.I. 1 [Compl.]).

The reason MonoSol has not alleged trade secret misappropriation is simple. MonoSol has not determined whether Par has misappropriated MonoSol's trade secrets. (D.I. 29 [Jan. 17, 2014 Hearing Tr.] at 53:22-54:1 ("Well, we precisely didn't bring a trade secret claim because we don't know what they're using or what technology they're using in their product.); *see also* D.I. 71-1

[10] This Court appears to agree. As the Court acknowledged, "There's no real controversy between the parties right now." (D.I. 78 [April 7, 2014 Hearing Tr.] at 45:3-4).

[Exs. 1-5 to April 3, 2014 Fineman Letter to Court regarding dispute over protective order] at Ex. 3, Interrogatory No. 2 Response ("MonoSol has not yet identified specific information in Par's ANDA that MonoSol believes independently, or necessarily, evidences Par's misappropriation of a MonoSol trade secret.").) As MonoSol does not even know if a trade secret has been misappropriated, MonoSol cannot in good faith take a position,[11] let alone an adverse position, regarding trade secret misappropriation. (D.I. 75 [April 4, 2014 Bourke Responsive Letter to Court regarding discovery dispute] at 3 ("At this time, MonoSol does not have a good faith basis to assert trade secret misappropriation and has refrained from doing so.")).

Par's characterization of the August 2, 2013 letter as an allegation of trade secret misappropriation by Plaintiffs is inaccurate.[12] (*See, e.g.*, D.I. 15 [Countercl.] ¶ 41.) The plain language of cited statement—"…MonoSol needs to be able to consider trade secret issues…"—makes it clear that Plaintiffs were not alleging that Par has misappropriated trade secrets, but rather—in context—Plaintiffs were seeking to make certain their legitimate review of Par's ANDA. It appears that Par recognizes the unreasonable characterization it has forced onto the language of the August 2, 2013 letter, as they have "always expected" a motion to dismiss based on the absence of an actual controversy. (D.I. 78 [April 7, 2014 Hearing Tr.] at 33:9-19).

As an actual controversy does not exist between Plaintiffs and Par regarding trade secrets, the Court lacks subject matter jurisdiction over Par's declaratory judgment counterclaim. For this reason, Par's counterclaim should be dismissed without prejudice, pursuant to Rule 12(b)(1).

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[11] FED. R. CIV. P. 11.

[12] Indeed, at one of several court appearances at which this issue was addressed, Par's counsel accepted "the denial by plaintiffs that such a controversy exists." (D.I. 78 [April 7, 2014 Hearing Tr.] at 33:11-12.)

IV. CONCLUSION

Accordingly, for the reasons stated above, Plaintiffs respectfully request that the Court grant Plaintiffs' Motion to Dismiss, without prejudice, all claims in this action against Defendants, as well as all of Defendants' counterclaims against Plaintiffs.

Dated: April 17, 2014
Redacted Version: April 24, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 17, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on April 17, 2014, upon the following individuals via electronic mail:

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